

recommendations would be preferable to a wage index that could be developed by the traditional rulemaking process, both for the hospice community as a whole, and for the Medicare beneficiaries it serves. The proposed rule announcing the revised hospice wage index, including a description of the methodology used to calculate the index, will be published in the spring of 1996. The Committee Statement signed by all committee members is reprinted below.

United States Department of Health and Human Services Negotiating Committee on the Medicare Hospice Wage Index

Committee Statement

April 13, 1995.

The Negotiating Committee on Medicare Hospice Wage Index has concurred in the following recommendations, considered as a whole, concerning the wage index used to adjust Medicare payment rates for hospice services to reflect geographic differences in wages:

A. Data to be Used

The wage index for hospices will be based on the wage index used by the Health Care Financing Administration (HCFA) for hospitals under the Medicare Prospective Payment System, prior to reclassification. This means that the hospital wage index will not be adjusted to take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(b) and 1886(d)(10) of the Social Security Act.

The hospital wage index prior to reclassification will be referred to in this statement as the Raw Index and will be adjusted as provided below to calculate what will be referred to as the Revised Wage Index.

Special provisions governing a transition period are described in paragraph D below.

B. Budget Neutrality

HCFA will determine a Budget Neutrality Factor that will be applied to achieve neutrality during and after the transition period. Budget neutrality means that, in a given year, estimated aggregate payments for Medicare hospice services using the Revised Wage Index will equal estimated payments that would have been made for the same services if the wage index adopted for hospices in 1983 (1983 Index) had remained in effect. HCFA will estimate aggregate payments for Medicare hospice services using the best available utilization data.

C. Adjustments

Each Raw Index value will be adjusted in one of two ways to determine the Revised Wage Index value applicable to each area.

(1) If the Raw Index value for any area is 0.8 or greater, the Revised Wage Index will be calculated by multiplying the Raw Index value for that area by the Budget Neutrality Factor.

(2) If the Raw Index value for any area is less than 0.8, the Revised Wage Index will be the greater of either:

(a) The Raw Index value for that area multiplied by the Budget Neutrality Factor; or

(b) The Raw Index value for that area multiplied by 1.15 (in effect, a 15-percent increase), but subject to a maximum index value of 0.8.

D. Transition Period

The Revised Wage Index will be implemented over a 3-year transition period beginning on or about October 1, 1996. For the first year of the transition period, a blended index will be calculated by adding two-thirds of each 1983 index value for an area to one-third of the Revised Wage Index value for that area. During the second year of the transition period, the calculation will be similar, except that the blend will be one-third of the 1983 Index values and two-thirds of the Revised Wage Index values. During the third year the Revised Wage Index will be fully implemented.

Throughout the transition period, new hospices will be treated the same as existing hospices based in the same county.

E. Annual Updates

The Revised Wage Index will be updated annually, so that it is based on the most current available data used by HCFA to construct the hospital wage index, as well as on changes by the Office of Management and Budget to Metropolitan Statistical Areas as adopted by HCFA in calculating the hospital wage index.

HCFA will use the most current hospital cost report data available that allows HCFA to publish a proposed rule containing wage index values at least 4 months in advance of the effective date of each annual update to the Revised Wage Index.

F. Effective Date

The effective date of a final rule revising the wage index as stated above should be October 1, 1996.

G. Statement to Accompany Proposed and Final Hospice Wage Index Notice

The proposed rule is based upon a Committee Statement developed by a Negotiating Committee on the Medicare hospice wage index which was convened under the Negotiated Rulemaking Act. A new hospice wage index is needed because the existing hospice wage index is based on a 1983 wage index using 1981 Bureau of Labor Statistics (BLS) data which is inaccurate and outdated.

The Committee reached consensus; however, this means only that all Committee members could "live with" the agreement, considered as a whole, even if elements of that agreement were not the preferred choice of individual Committee members. The Committee Statement reflects those issues upon which the Committee ultimately concurred, but does not address many issues that were considered by the Committee.

The Committee considered the appropriate data to be used to construct a wage index, the appropriateness of retaining a 0.8 floor, budget neutrality, and how to structure a transition to timely update the index yet ensure access to hospice care. In particular, the Committee considered the problems

faced by hospices that would receive significant decreases under the new wage indices, rural hospices, hospices with low wage indices, and hospices that may have disproportionately high non-wage costs.

The Committee received extensive information from experts who appeared before the Committee and from the hospice community, and sought public input. While considerable data was reviewed, the Committee acknowledges that hospice data collection is maturing and encourages its continued development. In addition, while other issues were identified, the scope of the Committee's negotiations was limited by the Notice of Intent to Negotiate.

Given these constraints, and taking into account the differing and conflicting interests that would be significantly affected, the Committee sought to develop a wage index that would be as accurate, reliable, and equitable as possible, but would not threaten access to hospice care.

The Committee recognizes that hospice care is still not universally available. The Committee further recognizes that there may be geographic or other circumstances that inhibit the provision of hospice care. The Committee strongly requests that HCFA consider options to address these access problems.

Reaching consensus was a long and deliberative process. The Committee concurred that the wage index it recommends will be better both for the hospice community as a whole, and for the Medicare beneficiaries it serves, than a wage index developed by the traditional rulemaking process.

Authority: Section 1814(i) of the Social Security Act (42 U.S.C. 1395(f)).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 25, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95-29140 Filed 11-28-95; 8:45 am]

BILLING CODE 4120-01-P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Health and Human Services Department.

ACTION: Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected

inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications and issued patents listed below may be obtained by writing to John Fahner-Vihtelic, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Box 13, Rockville, Maryland 20852-3804 (telephone 301/496-7735 ext 285; fax 301/402-0220). A signed Confidential Disclosure Agreement (CDA) will be required to receive copies of the patent applications. Requests for copies of issued patents do not require the execution of a CDA.

Methods For Determining The Presence Of Functional p53 In Mammalian Cells

Fornace, A.J., Kastan, M.B. (NCI)

Filed 10 Aug 94

Serial No. 08/288,872 (CON of 07/974,960)

The protein p53 is involved in tumorigenesis. Recent observations have indicated that the gene encoding p53 is a tumor suppressor gene; however, mutation or deletion of this gene results in loss of this suppressor function. Mutations of the p53 gene have been demonstrated in tumors of the colon, breast, lung, ovary, bladder, and other organs, making the p53 gene the most commonly mutated gene yet identified in human cancers. While currently used assays can detect the presence of wild-type or mutant p53 protein in mammalian cells, they cannot accurately determine the presence of functional p53 protein in these cells, which is necessary to determine the biological function of functional p53 and to develop subsequent diagnostic modalities using functional p53. This invention describes a specific gene whose expression is dependent on the presence of functional p53 in cells and tumors, as well as methods by which the presence of this gene may be detected. It also describes a diagnostic kit utilizing a nucleic acid sequence capable of binding functional p53, which is then measured to detect p53 presence. Issuance of a patent on this invention is currently pending. [portfolio: Cancer—Diagnostics]

Novel B-Lymphoma Cell Line And Antigen

Bock, G.H., Nelson, D.L., Kurman, C.C., Fleisher, T.A. (NCI)

Filed 9 Aug 94

Serial No. 08/287,718 (FWC of 07/934,106)

Various cell lines of B-cell lineage have been produced, but none have been of tumor cell origin. This case

provides an IL-6 dependent B-cell lymphoma cell line, designated DS-1. The invention further provides a monoclonal antibody which reacts with the cell line and a method for detecting the presence of neoplastic cells by detecting the presence of an antigen on a cell which is not normal for that cell type. [portfolio: Cancer—Diagnostics; Cancer—Research Reagents]

Novel Human ras-Related Oncogenes Unmasked By Expression cDNA Cloning

Aaronson, S., Chan, A., Miki, T. (NCI)

Filed 24 May 94

Serial No. 08/247,946

A family of small G-proteins encoded by H-, K-, and N-ras is frequently activated as oncogenes in a wide variety of human tumors. Activation is usually due to a point mutation within the coding sequence which results in the molecule to be constitutively in the GTP bound (active) state. In normal cells, these proteins are coupled to growth factor signaling pathways and appear to cause proliferation or differentiation. Over the past several years, cloning efforts by many laboratories have greatly expanded the number of ras-related proteins, to include R-ras, K-rev-1/rap and TC21. The present invention relates to a mutant TC21 protein that was cloned from an expression cDNA from a ovarian carcinoma cell line. Based upon the finding that an oncogenic form of TC21 exists, the present invention also relates to the generation of point mutations in R-ras for expression study. The present invention also relates to methods of diagnosing cancers or monitoring disease progression by detecting mutant forms of R-ras or TC21 at the protein or gene level. [portfolio: Cancer—Diagnostics; Cancer—Research Reagents]

Immortalized Adult Human Prostate Epithelial Cell Lines

Rhim, J.S., Webber, M.M. (NCI)

Filed 28 Apr 94

Serial No. 08/234,843

This invention relates to cell lines which are useful in testing compounds for anti-carcinogenic, anti-neoplastic, anti-invasive, or anti-metastatic activity by growing the cell line in the presence of the subject compounds. The cell lines contain DNA of a human Papilloma virus (HPV), either alone or with an activated viral ras oncogene, e.g., v-Ki-ras. The HPV immortalized line is not tumorigenic; however, the V-Ki-ras transformed HPV cell line is tumorigenic. They are useful for determining causes, treatment, and prevention of prostate cancer, benign

prostate hyperplastic, male infertility, birth defects, aging, and assessment of environmental toxic agents. [portfolio: Cancer—Research Reagents]

Pulsed Low Frequency EPR Spectrometer And Imager

Bourg, J., Cherukuri, M., Mitchell, J., Mirotznik, M., Roth, B., Subramanian, S. (NCI)

Serial No. 08/097,811

Patent Issued 7 Feb 95

U.S. Patent No. 5,387,867

This application describes an Electron Paramagnetic Resonance (EPR) spectroscopy imaging system. This system generates broadband pulses having a RF carrier frequency that is not highly absorbed by biological materials. The pulse generating system includes up and down chirp converters for frequency modulating of a carrier frequency and compression of the frequency modulated pulse to form a broadband excitation pulse of high energy. This technology's function has been proven and could form the basis of a clinical imaging device capable of high sensitivity to free radical species in human patients. [portfolio: Devices/Instrumentation—Diagnostics, electron paramagnetic resonance]

Phosphonoalkyl Phenylalanine Compounds Suitably Protected For Use In Peptide Synthesis

Burke, T.R., Smyth, M.S., Lim, B.B. (NCI)

Filed 8 Jun 93

Serial No. 08/073,088

A novel class of phosphononodifluoromethyl phenylalanine ("F₂Pmp") derivatives have been developed which are suitable for the synthesis of peptides containing the phosphotyrosyl (pTyr) mimetic, F₂Pmp. These analogues bear Boc or Fmoc protection at the N α -position for either solution or solid-phase peptide synthesis using standard techniques. A number of studies have shown that peptides containing the F₂Pmp residue show utility as inhibitors of src homology 2 (SH2) domain binding interactions and of phosphotyrosyl phosphatases. Unlike pTyr residues, the F₂Pmp moiety is stable to both chemical and phosphatase-mediated hydrolysis, making it an attractive replacement for pTyr in signal transduction peptides. [portfolio: Cancer—Research Reagents]

Monoclonal Antibodies To Prostate Cells

Pastan, I. (NCI)

Filed 8 Oct 92

Serial No. 07/958,140

Monoclonal antibodies which bind to an antigen associated with prostate cells, including prostate cancer, can be

used either individually or conjugated to drugs, labels, radioisotopes, or cytotoxins to target delivery of the conjugated to prostate cells. The antibodies are thus useful in a variety of diagnostic and therapeutic applications involving prostate cancer. A hybridoma cell line secreting monoclonal antibody PR1 is also provided, as well as methods for screening for the presence of metastatic prostate cancer. [portfolio: Cancer—Therapeutics]

Antibodies To Human LINE-1 p40 Protein

Fanning, T.G. (NCI)
Serial No. 07/750,044
Patent Issued 18 Jan 94
U.S. Patent No. 5,280,108

Antibodies to the human LINE-1 retrotransposon offer a powerful new tool for studying tumors. In most cell lines and tissues, human LINE-1 sequences (LIHs) are not expressed; however, LIH-specific RNA and proteins have been detected in cell lines and tissues derived from human germ cell tumors (teratocarcinomas) and breast tumors. These LIH antibodies, which are specific for the p40 protein portion of the retrotransposon, can be used for determining LIH expression in tumor cells and determining the role this retrotransposon plays in these cells. [portfolio: Cancer—Research Reagents]

Cartilage-Derived Morphogenetic Proteins

Luyten, F.P., Moos, M., Chang, S. (NIDR)
PCT Application PCT/US94/12814 filed 7 Nov 94
DHHS Reference No.: E-138-94/0

The present invention provides a cartilage-derived extract which initiates and promotes ectopic cartilage and bone development *in vivo* and recombinant cartilage-derived morphogenetic proteins which promote development of musculoskeletal tissues *in vivo*. These products will be useful in the therapeutic induction, repair, and maintenance of skeletal tissues. These compounds show promise for the healing of joint surface lesions and repair or reconstruction of cartilaginous tissues. They are also useful as growth factors for cells of the chondrocyte lineage which, expanded *ex vivo*, can be implanted into an individual where cartilage growth is desired. In addition, cloned polynucleotides encoding these proteins will be effective diagnostic reagents for detecting genetic abnormalities associated with poor skeletal development. [portfolio: Cancer—Therapeutics, biological response modifiers, growth factors]

Dated: November 20, 1995.
Barbara M. McGarey,
Deputy Director, Office of Technology Transfer.
[FR Doc. 95-29092 Filed 11-28-95; 8:45 am]
BILLING CODE 4140-01-P

National Cancer Institutes; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Cancer Institute Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Subcommittee D—Clinical Research Studies.

Date: December 11–12, 1995.

Time: 8 a.m.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: John Abrell, Ph.D., 6130 Executive Blvd., Room 635B, Bethesda, MD 20892, telephone: 301-496-9767.

Committee Name: Subcommittee H—Clinical Trials.

Date: December 12–13, 1995.

Time: 8 a.m.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: John L. Meyer, Ph.D., 6130 Executive Blvd., Room 611C, Bethesda, MD 20892, telephone: 301-496-7721.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(CATALOG OF FEDERAL DOMESTIC ASSISTANCE PROGRAM NUMBERS: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: November 21, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-29090 Filed 11-28-95; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Cancer Institute

Frederick Cancer Research & Development Center Advisory Committee.

Agenda/Purpose: Discussion of previous site visit report and response for the AIDS Vaccine program and AIDS projects both under contract with Science Applications International Corporation, site visit review of the Macromolecular Structure Laboratory with Advanced Bioscience Laboratories, Inc.

Committee Name: Frederick Cancer Research & Development Center Advisory Committee.

Date: December 11–13, 1995.

Time: Open Session, Dec. 11–8:30 a.m.–11:00 a.m.; closed session, Dec. 11–11 a.m.–Dec. 13.

Place: Frederick Cancer Research and Development Center, Building 549, Executive Board Room, Frederick, MD 21702.

Contact Person: Cedric W. Long, Ph.D., Frederick Cancer Research and Development Center, P.O. Box B, Frederick, MD 21702, telephone: 301-496-1108.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The reports and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(CATALOG OF FEDERAL DOMESTIC ASSISTANCE PROGRAM NUMBERS: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: November 21, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-29091 Filed 11-28-95; 8:45 am]

BILLING CODE 4140-01-M

Substance Abuse and Mental Health Services Administration

Proposed Data Collection Available for Public Comment

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide the opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration publishes periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the SAMHSA Reports Clearance Officer on (301) 443-0525.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance